

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			285	
Subject Qualification	07/21/03 mm dd yy	D, A, B F M L	Permanent #: 39	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>43</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ? <u>Squamous, tumor</u>		✓	
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ? <u>Bayer Aspirin 250mg taken when</u>		✓	

Comments:

needed for preventativeBased on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature:

Sharon E. Bocheidi

Date:

07/21/03

mm dd yy

Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-
Page No.: IV-4

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>D/A/B</u> f m i	<u>285</u> Permanent #: <u>39</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SEP, 7/21/03

Investigator's Signature: _____

Ann R. Brady

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>285</u>	Study #
Test Period	<u>07/30/03</u> mm dd yy	<u>D / A / B</u> F M L	Permanent #: <u>39</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments: _____

Interviewer's Signature: <u>Mary M. Wooten</u>	Date: <u>07/30/03</u> mm dd yy
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Data Collection Form 4

HTR Study No.: 03-122085

Page No.: IV 431

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/30/03</u> mm dd yy	<u>D A B</u> F M L	<u>285</u> Permanent #: <u>39</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10^{-4}	10^{-5}	10^{-6}	10^{-4}	10^{-5}	10^{-6}
TNTC	<u>206</u>	<u>20</u>	TNTC	<u>157</u>	<u>15</u>
TNTC	<u>146</u>	<u>14</u>	TNTC	<u>67</u>	<u>12</u>
CFU/mL <u>1.8×10^7</u> Counted by: <u>SP / 8/1/03</u>			CFU/mL <u>1.1×10^7</u> Counted by: <u>SP / 8/1/03</u>		

LEFT HAND				WASH 1		RIGHT HAND	
10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	
TNTC	TNTC	TNTC	<u>46</u>	TNTC	TNTC	TNTC	<u>2</u>
TNTC	TNTC	TNTC	<u>46</u>	TNTC	TNTC	TNTC	<u>4</u>
TNTC				TNTC			
CFU/mL <u>4.6×10^5</u> Counted by: <u>SP / 8/1/03</u>				CFU/mL <u>3.4×10^5</u> Counted by: <u>SP / 8/1/03</u>			

LEFT HAND				WASH 11		RIGHT HAND	
10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	
TNTC	TNTC <u>39</u>	<u>73</u>	<u>8</u>	TNTC	TNTC	<u>39</u>	
TNTC	TNTC <u>4</u>	<u>62</u>	<u>6</u>	TNTC	TNTC	<u>45</u>	
TNTC	<u>(3) PS 8-1-03</u>			TNTC			
CFU/mL <u>6.8×10^4</u> Counted by: <u>PS / 8-1-03</u>				CFU/mL <u>4.2×10^4</u> Counted by: <u>PS / 8-1-03</u>			

Calculations by: AS / 8-1-03 Raw data reviewed by JNB / 08-01-03Calculations Verified by: JNB / 08-01-03* 10^{-1} dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>Ann R. Brady</u>	Date: <u>08 / 19 / 03</u> mm dd yy
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Data Collection Form 5A

Subject Initials D.A.B. Subject # 39Study No. 03-122085-Page No. IV-432

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investiga Signature/
Cellulitis	7-31-03	8/13/03	N	2	2	1	4*	E. J. Jones
Entry Date	Comment/Note: * Probably due to test organism - E. J. Jones							
7-31-03	Swelling on back of right hand							
	around a puslath							
8/13/03	took 500mg tylenol 4x on 7/31/03							
8/13/03	hands & forearms clear							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investiga Signature/
Macules	see above for dates							8/13/03 gnr
Entry Date	Comment/Note:							
8-4-03	Three red macules on hands and forearms							
8/13/03	went to Dr. Jones office and was prescribed 500mg #20 cephalexin 1x day for 10 days							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investig Signature
Entry Date	Comment/Note:							

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild

2=Moderate

3=Severe

Relationship: 1=Definite

2=Probable

3=Possible

4=Unrelated

Action Taken: 1=None

2=Rx Therapy

3=Discontinued Study

4=Other (specify)

Outcome: 1=Resolved w/o sequelae

2=Resolved w/ sequelae (describe)

3=Ongoing

4=Death

DERMATOLOGY

HISTORY & PHYSICAL

DATE 7-31-03

NAME

DAVID BOONE

W D

INSURANCE

ADDRESS

1020 LOVELAND-MADIERA ROAD APT 10
LOVELAND, OH 45140

PHONE ()

()

DATE OF BIRTH

AGE

PROV. NO.

03

122085

PAGE NO.

TL

433

CHIEF COMPLAINT

Shen in bed

Duration

HISTORY OF
PRESENT ILLNESSOnset 7-15
7-31-03Was in Hall Top
Hard Work Stitches

MEDICATIONS

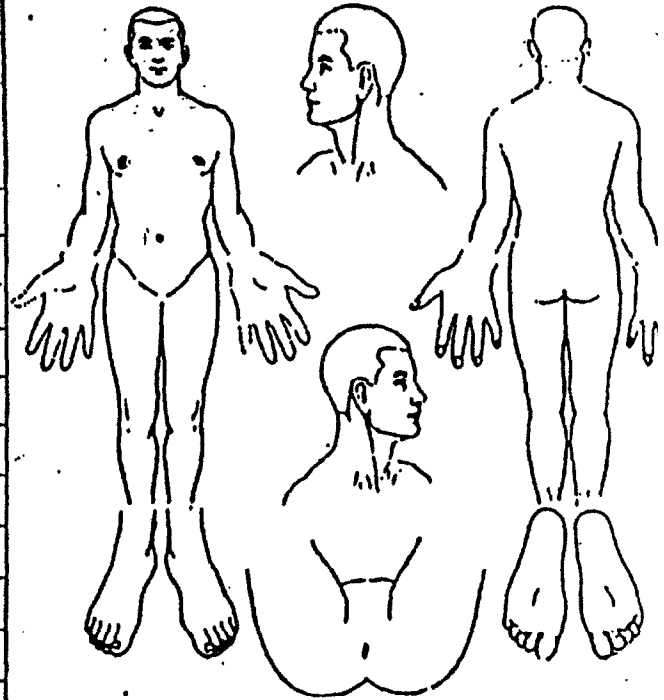
ALLERGIES

MEDICAL HISTORY

☐ ANEMIA☐ DIABETES☐ HEART☐ PEPTIC ULCER☐ LIVER☐ TUBERCULOSIS☐ KIDNEY☐ HYPERTENSION☐ CANCER☐ ASTHMA/HAYFEVER☐ ARTHRITIS☐ HIVES/EZEMA☐

FAMILY HISTORY

PHYSICAL EXAM



INVESTIGATIONS

DIAGNOSIS

Cellulitis

TREATMENT/PLANS

RX: CEPHLEXIN CAPSULES
500 MG #20 X/

SIG: CAP 1 B.I.D. FOR 10 DAYS

Pustule Drained

FOLLOW-UP VISIT

Page No.: IV-434

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>08/04/03</u> mm dd yy	<u>D A B</u> F M L	<u>285</u> Permanent #: <u>39</u>	03-122085-106

Date Subject Entered the Study:

07/21/03

mm dd yy

Follow-Up Visit Date:

08/04/03

mm dd yy

Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?

☒ YES☐ NO

If yes, complete below:

Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

Three red macules on hands and forearm.

Comments:

Has the subject had any health related issues since the treatment procedure?

☒ YES☐ NO

If yes, complete below

Comments:

a fever for one day 7-31-03Began antibiotics on 8-3-04

Medical Consultant's Signature:

E. Quinn Jones MD

Date

8/4/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>121</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>J - H</u> F M L	Permanent #: <u>40</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>43</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	<u>/</u>		
2. Eczema ?	<u>/</u>		
3. Skin Cancer ?	<u>/</u>		
4. Skin Allergies ? Please specify:	<u>/</u>		
5. Hives ?	<u>/</u>		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	<u>/</u>		
2. Hepatitis ?	<u>/</u>		
3. Heart and Vascular Disease?	<u>/</u>		
4. Liver Disease ?	<u>/</u>		
5. Kidney Disease ?	<u>/</u>		
6. Tuberculosis ?	<u>/</u>		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	<u>/</u>		
8. Cancer ?	<u>/</u>		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	<u>/</u>		
10. Organ transplant ?	<u>/</u>		
11. Any other condition not listed ? Please specify:	<u>/</u>		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	<u>/</u>		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	<u>/</u>		
3. Heart Medication ?	<u>/</u>		
4. Insulin ?	<u>/</u>		
5. Other ?	<u>/</u>		

Comments:

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature: <u>Gusman R. Harris</u>	Date: <u>07/15/03</u> mm dd yy
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Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: IV-436

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			<u>121</u>	
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>J/-/H</u> f m l	Permanent #:	03-122085-106
			<u>40</u>	

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <u>Tubal</u> <input checked="" type="checkbox"/> Surgically Sterile, year <u>1981</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SRH 7.15.03

Investigator's Signature: _____

Ann R. Bury

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>121</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>J - H</u> F M L	Permanent #: <u>40</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Betty M. Conover

Date: 07/23/03
mm dd yy

Data Collection Form 4

HTR Study No.: 03-122085-106

Page No.: IV 438

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u> mm dd yy	<u>J - H</u> F M L	<u>121</u>	
		Permanent #:	03-122085-106
		<u>40</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>182</u>	<u>14</u>	TNTC	<u>151</u>	<u>17</u>
TNTC	<u>162</u>	<u>31</u>	TNTC	<u>100</u>	<u>17</u>
CFU/mL <u>2.0 x 10⁷</u> Counted by: <u>JNB/07-25-03</u>			CFU/mL <u>1.2 x 10⁷</u> Counted by: <u>JNB/07-25-03</u>		

LEFT HAND				WASH 1		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
TNTC	TNTC	TNTC	<u>38</u>	TNTC	TNTC	<u>111</u>	<u>16</u>		
TNTC	TNTC	TNTC	<u>27</u>	TNTC	TNTC	<u>152</u>	<u>19</u>		
TNTC				TNTC					
CFU/mL <u>3.2 x 10⁵</u> Counted by: <u>JNB 07-25-03</u>				CFU/mL <u>1.3 x 10⁵</u> Counted by: <u>JNB 07-25-03</u>					

LEFT HAND				WASH 11		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
TNTC	TNTC	<u>156</u>	<u>15</u>	TNTC	TNTC	<u>58</u>	<u>6</u>		
TNTC	TNTC	<u>131</u>	<u>17</u>	TNTC	TNTC	<u>71</u>	<u>11</u>		
TNTC				TNTC					
CFU/mL <u>1.4 x 10⁵</u> Counted by: <u>JNB 07-25-03</u>				CFU/mL <u>6.4 x 10⁴</u> Counted by: <u>JNB 07-25-03</u>					

Calculations by: TG 17-26-03 Raw data reviewed by: AKB 18-1-03Calculations Verified by: JNB 07-29-03*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/11/03</u> mm dd yy
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FOLLOW-UP VISIT

Page No.: IV-439

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>07/28/03</u> mm dd yy	<u>J - H</u> F M L	<u>121</u> Permanent #: <u>40</u>	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: <u>07/28/03</u> mm dd yy
<p>Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below:</p> <p>Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	
<p>Has the subject had any health related issues since the treatment procedure?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	

Medical Consultant's Signature: <u>[Signature]</u>	Date <u>7/28/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			185	
Subject Qualification	07/21/03 mm dd yy	L/-/N F M L	Permanent #: 41	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: 55 Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. <u>environmental</u>		✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: <u>HRT</u>		✓	

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ? <u>Vivelle. 0.05 patch HRT</u>		✓	

Comments:

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature: <u>Jami Busmeyer</u>	Date: <u>07/21/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-441

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	<u>07/21/03</u>	<u>L - N</u>	<u>185</u>	
Subject Qualification	mm dd yy	f m l	Permanent #:	03-122085-106
			<u>41</u>	

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year <u>1991</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB 107-21-03

Investigator's Signature: Ann R. Brady Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>185</u>	Study #
Test Period	<u>07/28/03</u> mm dd yy	<u>L1-IN</u> F M L	Permanent #: <u>NA</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: extra subject 11 subject returned on 7/30/03 gsn

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments: _____

Interviewer's Signature: <u>Mary M. Wetherham</u>	Date: <u>07/28/03</u> mm dd yy
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Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>185</u>	Study #
Test Period	<u>07 / 30 / 03</u> mm dd yy	<u>L / - / N</u> F M L	Permanent #: <u>41</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: <u>Mary M. Wouten</u>	Date: <u>07 / 30 / 03</u> mm dd yy
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Data Collection Form 4

HTR Study No.: 03-122085-106

Page No.: IV 444a

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/30/03</u> mm dd yy	<u>L / - / N</u> F. M L	<u>185</u> Permanent #: <u>41</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10^{-4}	10^{-5}	10^{-6}	10^{-4}	10^{-5}	10^{-6}
TNTC	<u>165</u>	<u>19</u>	TNTC	<u>158</u>	<u>18</u>
TNTC	<u>114</u>	<u>15</u>	TNTC	<u>193</u>	<u>LA*</u>
CFU/mL <u>1.4×10^7</u> Counted by: <u>SP / 8/1/03</u>			CFU/mL <u>1.8×10^7</u> Counted by: <u>SP / 8/1/03</u>		

LEFT HAND				WASH 1		RIGHT HAND		
10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}	
TNTC	TNTC	<u>48</u>	<u>4</u>	TNTC	TNTC	<u>86</u>	<u>10</u>	
TNTC	TNTC	<u>51</u>	<u>5</u>	TNTC	TNTC	<u>73</u>	<u>13</u>	
TNTC				TNTC				
CFU/mL <u>5.0×10^4</u> Counted by: <u>SP / 8/1/03</u>				CFU/mL <u>8.0×10^4</u> Counted by: <u>SP / 8/1/03</u>				

LEFT HAND				WASH 11		RIGHT HAND		
10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}	
TNTC	<u>81</u>	<u>9</u>	<u>0</u>	<u>241</u>	<u>107</u>	<u>7</u>	<u>1</u>	
TNTC	<u>87</u>	<u>5</u>	<u>0</u>	<u>189</u>	<u>39</u>	<u>6</u>	<u>0</u>	
TNTC				<u>186</u>				
CFU/mL <u>8.4×10^3</u> Counted by: <u>SP / 8/1/03</u>				CFU/mL <u>6.9×10^3</u> Counted by: <u>SP / 8/1/03</u>				

Calculations by: ARS / 8-1-03 Raw data reviewed by JNB / 08-01-03Calculations Verified by: ARS / 8-1-03* 10^{-1} dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

*LA = Lab Accident SP 8/1/03

Investigator's Signature: <u>Ann R. Brady</u>	Date: <u>08 / 10 / 03</u> mm dd yy
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FOLLOW-UP VISIT

Page No.: IV-445

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>08/04/03</u> mm dd yy	<u>L - N</u> F M L	<u>135</u> Permanent #: <u>41</u>	03-122085-106

Date Subject Entered the Study:

07/21/03

mm dd yy

Follow-Up Visit Date:

08/04/03

mm dd yy

Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?

☐ YES☒ NO

If yes, complete below:

Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

Comments:

Has the subject had any health related issues since the treatment procedure?

☐ YES☒ NO

If yes, complete below

Comments:

Medical Consultant's Signature:

E. Lynn Jones MD

Date

8/4/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>279</u>	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>R / K / B</u> F M L	Permanent #: <u>42</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>54</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	/		
2. Eczema ?	/		
3. Skin Cancer ?	/		
4. Skin Allergies ? Please specify:	/		
5. Hives ?	/		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.	/		
2. Hepatitis ?	/		
3. Heart and Vascular Disease?	/		
4. Liver Disease ?	/		
5. Kidney Disease ?	/		
6. Tuberculosis ?	/		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	/		
8. Cancer ?	/		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	/		
10. Organ transplant ?	/		
11. Any other condition not listed ? Please specify:	/		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	/		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	/		
3. Heart Medication ?	/		
4. Insulin ?	/		
5. Other ?	/		

Comments:

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature:

Stacey E. Bachardi

Date:

07/21/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-447

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	<u>07/21/03</u> mm dd yy	<u>R/K/B</u> f m l	<u>279</u> Permanent #: <u>42</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year <u>1974</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β-HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SRB 7/21/03

Investigator's Signature: _____

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Test Period	<u>07/30/03</u> mm dd yy	<u>R/K/B</u> F M L	<u>279</u> Permanent #: <u>42</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Mary M. Wenthom

Date: 07 / 30 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/30/03</u> mm dd yy	<u>R/K/B</u> F M L	<u>279</u> Permanent #: <u>42</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
1311 ESPC ^(*) ^(*)	LA **	<u>14</u>	TNTC	<u>169</u>	<u>27</u>
613 ESPC ^(*) ^(*)	LA **	<u>22</u>	TNTC	<u>154</u>	<u>15</u>
CFU/mL <u>9.6 × 10⁶</u> Counted by: <u>SP / 8/1/03</u> <u>1.7 × 10⁷ @ 38.1.03</u>			CFU/mL <u>1.9 × 10⁷</u> Counted by: <u>SP / 8/1/03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³ ^{SP}	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴				
TNTC	TNTC	<u>59</u> <u>59</u>	<u>3</u>	TNTC	TNTC	<u>56</u>	<u>1</u>				
TNTC	TNTC	<u>56</u>	<u>6</u>	TNTC	TNTC	<u>64</u>	<u>7</u>				
TNTC				TNTC							
CFU/mL <u>5.8 × 10⁴</u> Counted by: <u>SP / 8/1/03</u>				CFU/mL <u>6.0 × 10⁴</u> Counted by: <u>SP / 8/1/03</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴				
TNTC	<u>108</u>	<u>10</u>	<u>1</u>	TNTC	<u>237</u>	<u>18</u>	<u>3</u>				
TNTC	<u>154</u>	<u>21</u>	<u>1</u>	TNTC	<u>263</u>	<u>24</u>	<u>4</u>				
TNTC				TNTC							
CFU/mL <u>1.3 × 10⁴</u> Counted by: <u>PS / 8-1-03</u>				CFU/mL <u>2.4 × 10⁴</u> Counted by: <u>PS / 8-1-03</u>							

Calculations by: PS / 8-1-03 Raw data reviewed by: MS / 8-1-03Calculations Verified by: MS / 8-1-03*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

⊛ Did not estimate due to countability of plates. ^{PS 8/6}

**LA = LAB ACCIDENT ^{SP} 8/1/03 Contamination other than the master ^{SP} 8/1/03

⊛ ESPC = Estimated Standard Plate Count ^{SP 8/5/03}

Investigator's Signature: [Signature]Date: 8 / 14 / 03
mm dd yy

Data Collection Form 5A

Subject Initials RK B Subject # 42Study No. 03-122085-106Page No. IV-456

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Macules	8-4-03	8/8/03	N	1	1	1	4X	E. J. [Signature]
Entry Date	Comment/Note: * Probably due to test organism - E. J. [Signature]							Initials
8-4-03	One red macule on the right wrist							8-21-03
8/8/03	Wrist clear no medications used							gk

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild 2=Moderate 3=Severe

Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated

Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)

Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

Page No.: IV-451

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>08/04/03</u> mm dd yy	<u>R K B</u> F M L	<u>279</u> Permanent #: <u>42</u>	03-122085-106

Date Subject Entered the Study: <u>07/21/03</u> mm dd yy	Follow-Up Visit Date: <u>08/04/03</u> mm dd yy
<p>Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?</p> <p><input checked="" type="checkbox"/> YES <input type="checkbox"/> NO If yes, complete below:</p> <p>Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)</p> <p><u>One red nodule on right wrist</u> <u>Onset 8-4-03</u></p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>Has the subject had any health related issues since the treatment procedure?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	

Medical Consultant's Signature: <u>E. J. [Signature]</u>	Date <u>8/4/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>130</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>J I L I C</u> F M L	Permanent #: <u>43</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>59</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	<input checked="" type="checkbox"/>		
2. Eczema ?	<input checked="" type="checkbox"/>		
3. Skin Cancer ?	<input checked="" type="checkbox"/>		
4. Skin Allergies ? Please specify:	<input checked="" type="checkbox"/>		
5. Hives ?	<input checked="" type="checkbox"/>		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	<input checked="" type="checkbox"/>		
2. Hepatitis ?	<input checked="" type="checkbox"/>		
3. Heart and Vascular Disease?	<input checked="" type="checkbox"/>		
4. Liver Disease ?	<input checked="" type="checkbox"/>		
5. Kidney Disease ?	<input checked="" type="checkbox"/>		
6. Tuberculosis ?	<input checked="" type="checkbox"/>		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	<input checked="" type="checkbox"/>		
8. Cancer ? <u>Cancer (breast) in remission since 1986</u> ⁰⁷⁻¹⁵⁻⁰³	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	<input checked="" type="checkbox"/>		
10. Organ transplant ?	<input checked="" type="checkbox"/>		
11. Any other condition not listed ? Please specify: <u>see below **</u>		<input checked="" type="checkbox"/>	

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	<input checked="" type="checkbox"/>		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	<input checked="" type="checkbox"/>		
3. Heart Medication ?	<input checked="" type="checkbox"/>		
4. Insulin ?	<input checked="" type="checkbox"/>		
5. Other ? <u>Evista 60mg 1x day osteoporosis prevention **</u>		<input checked="" type="checkbox"/>	

Comments: Calcium + Vitamins 1x dayBased on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature: <u>Jamie Busermeyer</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-453

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>J/L/C</u> f m l	<u>130</u> Permanent #: <u>43</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input checked="" type="checkbox"/> Post-menopausal, year <u>1994/1995</u> If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive <u>(3) JNB 07-15-03</u>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB, 07-15-03

Investigator's Signature: <u>Ann R. Brady</u>	Date: <u>08/10/03</u> mm dd yy
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Data Collection Form 3
INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			<u>130</u>	
Test Period	<u>07/23/03</u> mm dd yy	<u>J/L/C</u> F M L	Permanent #: <u>43</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No
If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No
If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments: _____

Interviewer's Signature: <u>Sharon R. Harris</u>	Date: <u>07 / 23 / 03</u> mm dd yy
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HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u> mm dd yy	<u>J/L/C</u> F. M L	<u>130</u> Permanent #: <u>43</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>138</u>	<u>14</u>	TNTC	<u>162</u>	<u>22</u>
TNTC	<u>156</u>	<u>13</u>	TNTC	<u>190</u>	<u>19</u>
CFU/mL <u>1.5 x 10⁷</u> Counted by: <u>Qh 17/25/03</u>			CFU/mL <u>1.8 x 10⁷</u> Counted by: <u>Qh 17.25.03</u>		

LEFT HAND				WASH 1		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
TNTC	TNTC	<u>198</u>	<u>29</u>	TNTC	TNTC	<u>101</u>	<u>7</u>		
TNTC	TNTC	<u>179</u>	<u>19</u>	TNTC	TNTC	<u>129</u>	<u>16</u>		
TNTC				TNTC					
CFU/mL <u>2.1 x 10⁵</u> Counted by: <u>Qh 17.25.03</u>				CFU/mL <u>1.2 x 10⁵</u> Counted by: <u>Qh 17.25.03</u>					

LEFT HAND				WASH 11		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
TNTC	TNTC	<u>168</u>	<u>14</u>	TNTC	TNTC	<u>72</u>	<u>13</u>		
TNTC	TNTC	<u>180</u>	<u>24</u>	TNTC	TNTC	<u>97</u>	<u>12</u>		
TNTC				TNTC					
CFU/mL <u>1.7 x 10⁵</u> Counted by: <u>Qh 17.25.03</u>				CFU/mL <u>8.7 x 10⁵</u> Counted by: <u>Qh 17.25.03</u>					

② 76 7.26.03Calculations by: TG 17.26.03 Raw data reviewed by Alb 18.1.03Calculations Verified by: JNB 107.29.03*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/11/03</u> mm dd yy
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Data Collection Form 5A

Subject Initials √LC Subject # 43Study No. 03-122085-106Page No. IV-456

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Papules	7-27-03	8/1/03	N	1	1	1	4*	E. J. [Signature] 8-21-03
Entry Date	Comment/Note: * Probably due to test organism. E. J. 8-21-03							
7-28-03	Three red papules on the wrists and forearms.							
8/1/03	Hands & wrist clear - no medications used							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild 2=Moderate 3=Severe

Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated

Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)

Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

Page No.: IV-457

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>07/28/03</u> mm dd yy	<u>J L C</u> F M L	<u>130</u> Permanent #: <u>43</u>	03-122085-106

Date Subject Entered the Study:

07/15/03

mm dd yy

Follow-Up Visit Date:

07/28/03

mm dd yy

Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?

☒ YES ☐ NO If yes, complete below:

Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

Three red papules on wrists and forearms
Onset on 7-27-03

Comments:

Has the subject had any health related issues since the treatment procedure?

☐ YES ☒ NO If yes, complete below

Comments:

Medical Consultant's Signature:

E. Linn J. J. M.D.

Date

7/28/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			132	
Subject Qualification	07/15/03 mm dd yy	B / A / G F M L	Permanent #: 44	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: 21 Years
--	---------------

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. environmental	✓	✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature:

Danni Busmeyer

Date: 07/15/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-
Page No.: IV-6

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>B.A.G</u> f m l	<u>132</u> Permanent #: <u>44</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year <u> </u> <input type="checkbox"/> Post-menopausal, year <u> </u> If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive <u>7/23/03 ggn</u>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: JNB 107/15/03

Investigator's Signature: _____

Ann R. Brady

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>132</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>B / A / G</u> F M L	Permanent #: <u>44</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments: _____

Interviewer's Signature: Susan R. Harris

Date: 07 / 23 / 03
mm dd yy

Data Collection Form 4

HTR Study No.: 03-122085-
Page No.: IV-46

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u> mm dd yy	<u>B. A. G</u> F. M. L	<u>132</u> Permanent #: <u>44</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>116</u>	11	TNTC	<u>160</u>	19
TNTC	<u>150</u>	15	TNTC	<u>128</u>	11
CFU/mL <u>1.3 x 10⁷</u> Counted by: <u>AKB 17.25.03</u>			CFU/mL <u>1.4 x 10⁷</u> Counted by: <u>AKB 17.25.03</u>		

LEFT HAND				WASH 1		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	1
TNTC	TNTC	<u>138</u>	9	TNTC	TNTC	<u>79</u>	2
TNTC	TNTC	<u>120</u>	17	TNTC	TNTC	<u>102</u>	9
TNTC				TNTC			
CFU/mL <u>1.3 x 10⁵</u> Counted by: <u>AKB 17.25.03</u>				CFU/mL <u>9.0 x 10⁴</u> Counted by: <u>AKB 17.25.03</u>			

LEFT HAND				WASH 11		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	1
TNTC	TNTC	<u>77</u>	7	TNTC	TNTC	<u>72</u>	8
TNTC	TNTC	<u>84</u>	9	TNTC	TNTC	<u>67</u>	3
TNTC				TNTC			
CFU/mL <u>8.0 x 10⁴</u> Counted by: <u>AKB 17.25.03</u>				CFU/mL <u>6.8 x 10⁴</u> Counted by: <u>AKB 17.25.03</u>			

Calculations by: TG 17.26.03 Raw data reviewed by JNB 108.01.03Calculations Verified by: JNB 107.29.03*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>B. Mully</u>	Date: <u>0</u> <u>11</u> <u>103</u> mm dd yy
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Data Collection Form 5A

Subject Initials BAG Subject # 44Study No. 03-122085-1Page No. IV-462

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/D
red bumps w/itching	7/24/03	8/15/03	N	1	4(1)	1	4(2)	<i>[Signature]</i>
Entry Date	Comment/Note: 1) Used Non Rx cortisone cream → Due to test experience							
7/25/03	red bumps with itching on both hands							
8/15/03	Cortisone cream used 2 times on							
	7/28/03. Hands clear							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/D
see above for dates	8/15/03	grn						
Entry Date	Comment/Note:							
	Has used cortisone cream.							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/I
Entry Date	Comment/Note:							

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild 2=Moderate 3=Severe

Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated

Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)

Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

¹Serious Adverse Event/Experience